

09/967223

SCHERING-PLOUGH CORPORATION  
LAW DEPARTMENT  
2000 GALLOPING HILL ROAD  
K-6-1, MAIL STOP 1990  
KENILWORTH, NEW JERSEY 07033  
(908) 298-4000

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(908) 298-5067

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NOTES/COMMENTS:

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In re Application of: Seoju Lee  
For Patent For: "Pegylated Interleukin-10"  
Group Art Unit: 1616  
Attorney Docket No.: JB01337K US/ Serial No.: 09/967,223  
Filed: 09/28/2001  
U.S. Patent No.: 7,052,686 B2

Dear Examiner:

Transmitted here with are:

- Fax Cover Sheet - 1 Page
- Certificate of Transmission under 37 C.F.R. 1.8 PTO/SB/97 - 1 Page
- Petition to Correct Errors on Issued Patent Under C.F.R. 1.322 - 1 Page
- Certificate of Correction PTO/SB/44 - 1 Page (in duplicate)
- Copy of Claim Page of U.S. Patent 7,052,686 B2 - 1 Page

  
Grant E. Reed  
Registered Representative  
Registration No. 41,264

PHONE: (908) 298-5067

FAX: (908) 298-5388

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Docket Number: JB01337K US  
Application No: 09/967,223  
Filing Date: 09/28/2001  
First Inventor: LEE, Seju

PTO/SB/97 (09-04)  
Approved for use through 07/31/2008. OMB 0851-0031  
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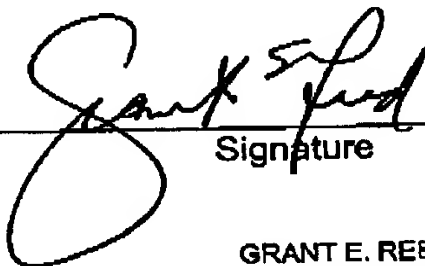
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- Certificate of Correction PTO/SB/44 - 1 Page (in duplicate)
- Copy of Claim Page of U.S. Patent 7,052,686 B2 - 1 Page

This collection of information is required by 37 CFR 1.8. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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2006

JUN 16 2006

PATENT CASE JB01337K

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE-----X  
In re Application of

Seoju Lee J.

Appln. No.: 09/967,223

Filed: September 28, 2001

Patent No. 7,052,686 B2

For: "Pegylated Interleukin-10":  
-----X

Examiner: Edward J. Webman

Group Art Unit: 1616

Issue date: May 30, 2006

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of Correction

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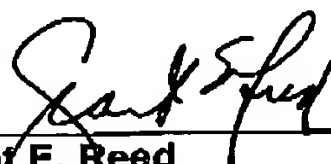
PETITION TO CORRECT ERRORS ON ISSUED PATENT

Petition is hereby made under 37 CFR §§ 1.322 to correct some errors in the claims of the above-identified issued patent. The errors are noted on Form PTO/SB/44 enclosed herewith.

Applicants respectfully submit that the above-noted errors are the fault of the Office. Accordingly, no fee is believed due. Issuance of a Certificate of Correction is respectfully requested. If there are questions, the undersigned Attorney-of-Record can be contacted.

June 16, 2006  
SCHERING-PLOUGH CORPORATION  
Patent Department, K-6-1, 1990  
2000 Galloping Hill Road  
Kenilworth, New Jersey 07033-0530  
Telephone: (908) 298-5068  
Facsimile: (908) 298-5388

Respectfully submitted,

  
Grant E. Reed  
Reg. No. 41,264  
Senior Counsel, Patents

Docket Number: JB01337K US  
Application No: 09/967,223  
Filing Date: 09/28/2001  
Express Mail Label: Via Facsimile

PTO/SB/44 (04-04)  
Approved for use through 04/30/2007. OMB 0651-0033  
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(Also Form PTO-1050)

**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

FILING DATE: 09/28/2001  
PATENT NO. : 7,052,686 B2  
DATED : 05/30/2006  
INVENTOR(S) : LEE, Seju

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

10. A process for preparing a pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 1, comprising mixing the mono-PEG-IL-10 with pharmaceutically acceptable carrier.

**MAILING ADDRESS OF SENDER:**

GRANT E. REED, Reg. No. 41,26  
Schering-Plough Corporation, Patent Dept, K-6-1, 1990  
2000 Galloping Hill Road, Kenilworth NJ 07033-0530

PATENT NO. 7,052,686 B2

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**DUPLICATE**

Docket Number: JB01337K US  
Application No: 09/967,223  
Filing Date: 09/28/2001  
Express Mail Label: Via Facsimile

PTO/SB/44 (04-04)  
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**PATENT NO. 7,052,686 B2**

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JUN 16 2006

## US 7,052,686 B2

## 15

10. A process for preparing a pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 1, comprising mixing the mono-PEG-IL-10 with a pharmaceutically acceptable carrier.

11. The mono-PEG-IL-10 according to claim 1, wherein the IL-10 is human IL-10.

12. A pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 11 and a pharmaceutical carrier.

13. The mono-PEG-IL-10 according to claim 11, wherein the PEG molecule has a molecular weight of 12,000 or 20,000 daltons.

14. A pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 13 and a pharmaceutical carrier.

15. A pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 1 in combination with a pharmaceutically acceptable carrier.

16. A method of treating inflammation in an individual in need of such treatment, comprising administering to the individual a therapeutically effective amount of the pharmaceutical composition according to claim 15.

17. A process for preparing the mono-PEG-IL-10 according to claim 1, comprising the step of:  
reacting IL-10 with an activated PEG-aldehyde linker in the presence of a reducing agent to form the mono-PEG-IL-10 under conditions in which the linker is covalently attached to one amino acid residue of the IL-10.

## 16

18. The process according to claim 17 wherein:

(a) the reducing agent is sodium cyanoborohydride;

(b) the activated PEG-aldehyde linker is PEG-propionaldehyde;

(c) the PEG is a methoxy-PEG;

(d) the linker is multi-armed;

(e) the ratio of IL-10 to the sodium cyanoborohydride is from about 1:0.5 to 1:50;

(f) the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 3,000 daltons to 60,000 daltons; or

(g) the reacting step is performed at a pH of 5.6 to 7.8.

19. The process according to claim 17, wherein the ratio of IL-10 to the sodium cyanoborohydride is 1:5 to 1:15.

20. The process according to claim 17, wherein the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 10,000 daltons to 36,000 daltons.

21. The process according to claim 17, wherein the reacting step is performed at a pH of 6.3 to 7.5.

22. The process according to claim 17, further comprising a step selected from:

incubating the mono-PEG-IL-10 product in a buffer at pH 5.0 to 9.0; or

treating the mono-PEG-IL-10 product with 0.05 to 0.4 M hydroxylamine HCl salt.

\* \* \* \* \*

E22012  
Claim 16  
Line 2

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